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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,314	06/29/2000	Richard Fike	0942.4290005/RWE/BJD	1340
26111	7590	12/21/2004		
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/606,314

Applicant(s)

FIKE ET AL.

Examiner

Michele Flood

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27,36,44-46,70,72,92-95,103 and 105-109 is/are pending in the application.
- 4a) Of the above claim(s) 44-46,70,72 and 105-109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,36,92-95 and 103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 27, 36, 92-95 and 103 in the reply filed on September 24, 2004 is acknowledged.

Claims 27, 36, 92-95 and 103 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 36, 92-95 and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Pebbles () and Getler et al. (AB4), as evidenced by the teachings of Ellington et al. (B), BBL Manual of Products and Laboratory Procedures (U), and Fassolitis et al. (V).

Applicant claims an agglomerated eukaryotic cell culture medium powder prepared by agglomerating a dry powder eukaryotic cell culture medium with a solvent; wherein said agglomerated powder, upon being reconstituted with water, supports the cultivation of a eukaryotic cell *in vitro*. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said eukaryotic cell culture medium has a pH of between 7.1-7.5 when said medium is reconstituted with a solvent,

Art Unit: 1654

wherein said solvent is water or serum. Applicant further claims the medium powder of claim 27, wherein said medium powder exhibits reduced dusting in comparison to a medium powder that is non-agglomerated; wherein said medium powder exhibits more rapid dissolution in comparison to a medium powder that is non-agglomerated; wherein said medium powder exhibits reduced dusting and more rapid dissolution in comparison to a medium powder that is non-agglomerated. Applicant further claims the medium powder of any one of claims 92-94, wherein the non-agglomerated medium powder is a lyophilized or ball-milled powder. Applicant further claims the agglomerated eukaryotic cell culture medium powder of claim 27, wherein said solvent is water, serum, aqueous acid or base.

Peebles teaches a method of obtaining a dried milk powder, which comprises lactose and milk protein, by agglomerating a spray-dried powder with water vapor and droplets of moisture. See Column 2, lines 13-70. The particulate matter of the dried milk powder taught by Peebles is of a size substantially greater than the particle size of the original powder, is readily dispersible in water, and has reduced dusting. See claims and Column 9, lines 46-54.

Getler teaches agglomerated milk products and milk-like products which are made in a two-stage agglomeration process comprising spray drying a pre-agglomerated concentrated premix by return of fine particles to an atomizer and, in a subsequent step, post-agglomeration by wetting and drying in a fluidized bed. The agglomerated dried products taught by Getler comprise the following ingredients: whey protein concentrates (see page 1, lines 11-14); and a fat component mixed with water, vitamins,

Art Unit: 1654

and with raw materials in powder form, *i.e.*, casein, whey, skim milk, malto dextrine, *etc.*

See page 1, line 36 to page 7, line 2. In Example 3, Getler teaches an agglomerated powder that exhibits reduced dusting and rapid dissolution.

With regard to the claim limitation "wherein said agglomerated powder upon being reconstituted with water supports the cultivation of a eukaryotic cell *in vitro*" of Claim 1, as evidenced by the teachings of Ellington, BBL Manual of Products and Fassolitis, the referenced agglomerated powders taught by Peebles and Getler are deemed to inherently possess the claim-designated limitation because it is notoriously old and well known in the art of microbiology that milk and milk products contain the appropriate components to allow the cultivation of a eukaryotic cells, as evidenced by the teachings of Ellington despite Ellington's seemingly lack of demonstration for the assertion that dry powdered skim milk or any dry powdered milk product can support the cultivation of eukaryotic cells *in vitro*. For instance, on page 162, under "Skim Milk", the BBL Manual of Products and Laboratory Procedures teaches a dehydrated skim milk powder, which "may be rehydrated and used as a complete medium, or may be incorporated into other media" for the identification of bacteria on the basis of their ability to coagulate or peptonize milk. In another example, on page 161, the BBL Manual of Products and Laboratory Procedures teaches a "Milk-Protein Hydrolysate", which is used for general bacteriological culture work. Moreover, its nutritive values are described as "excellent because of the comprehensive amino acid content." More related to the scope of the limitations of the instantly claimed invention, Fassolitis teaches a method for the cultivation and/or growth of eukaryotic cells, *i.e.*, epithelial

Art Unit: 1654

cells, using a powdered nonfat dry skim milk filtrate (NDMF) as an eukaryotic cell culture medium. See page 201, Column 1, under "Preparation of milk fraction", wherein Fassolitis teaches a method of making NDMF comprising reconstituting a dry milk powder. On page 200, Column 2, under "Cell culture medium", Fassolitis teaches a cell culture medium supplemented with 5% NDMF, and adjusted to a pH of 6.8 to 7.4 that is used to propagate epithelial cells (see Table 1 on page 201). Thus, as evidenced by BBL Manual of Products and Laboratory Procedures and Fassolitis, the prior art agglomerated dry powders taught by Peebles and Getler are deemed agglomerated eukaryotic cell culture medium powders that are able to support the cultivation of a eukaryotic cell *in vitro* upon reconstituted with water and inherently have the claim-designated pH range. Moreover, Ellington clearly teaches that cell culture media comprising milk products, e.g., skim milk, support the cultivation of eukaryotic cells. See Column 5, lines 29-44.

The references anticipate the claimed subject matter.

Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PATENT EXAMINER
MCF

December 16, 2004